

K061220  
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## 5. 510(k) Summary

### Premarket Notification Summary

1. Sponsor Information:  
Laboratories URGO  
42 Rue de Longvic  
21300 Chenove  
France

JUL 27 2006

Contact Person: Sophie Fortin  
Regulatory Affairs Manager  
Phone: +33.(0)3.80.44.79.67  
Fax: +33.(0)3.80.44.71.40

2. Device Name:  
Common or Usual Name: Antimicrobial Wound Dressing with Silver  
Proprietary Name: Urgotul® Ag  
Classification Name: Unclassified
3. Predicate Devices:  
Contreet-H Antibacterial Hydrocolloid Dressing (K013525), Coloplast Corp.  
Acticoat-7 Dressing (K001519), Smith & Nephew
4. Description of Device  
Urgotul® Ag wound dressing is a sterile, antimicrobial hydrocolloid wound contact dressing with silver.  
  
Urgotul® Ag wound dressing is non-occlusive and non-adhesive for painless removal.  
  
Urgotul® Ag is composed of a polyester mesh impregnated with a matrix of carboxymethylcellulose hydrocolloid particles, cohesion polymers and Vaseline containing silver.
5. Indications for Use  
The barrier functions of Urgotul® Ag Antimicrobial Wound Dressing may help reduce infection in light to moderately exudative partial and full thickness wounds, including diabetic ulcers, first and second degree burns, decubitus ulcers, venous stasis ulcers, and graft and donor sites.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 27 2006

Laboratories URGO  
% Ms. Sophie Fortin  
Regulatory Affairs Manager  
42 Rue de Longvic  
21300 Chenove  
France

Re: K061220  
Trade/Device Name: Urgotul® Ag  
Regulatory Class: Unclassified  
Product Code: FRO  
Dated: April 5, 2006  
Received: May 1, 2006

Dear Ms. Fortin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

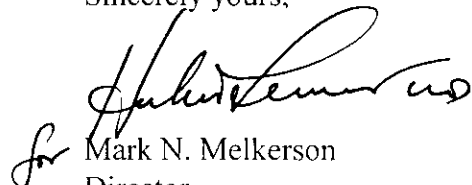
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Sophie Fortin

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", is written over the typed name.

Mark N. Melkerson

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

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1/1

## Indications for Use

510(k) Number (if known): K 061220

Device Name: Urgotul® Ag

### Indications For Use:

The barrier functions of Urgotul® Ag Antimicrobial Wound Dressing may help reduce infection in light to moderately exudative partial and full thickness wounds, including diabetic ulcers, first and second degree burns, decubitus ulcers, venous stasis ulcers, and graft and donor sites.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER  
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

Revision submitted 26/07/06 following FDA request

510(k) Number K061220